

Amendment to the Drawings:

The attached sheets of drawings include changes to Figs. 5-36. These sheets replace the original sheets of Figs. 5-36.

Attachment: Replacement Sheet

REMARKS/ARGUMENTS

Applicants respectfully request reconsideration of this application. By the amendments, Applicants do not acquiesce to the propriety of any of the Office's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

In the Drawings

The drawings have been objected to because they were not clear. Applicants re-submit herewith formal drawings of Figures 5-36 previously submitted to the Office on July 10, 2006 and to the Office as the Receiving Office and the International Bureau on May 4, 2005. Applicants respectfully assert that the attached version of Figures 5-36 overcomes the Office's objections. If there are objections to the drawings remaining, Applicants respectfully request clarification from the Office on the nature of the objections.

In the Claims

Claims 1, 2, 5, 8-10, 12, 13, 16, 18, 20-22, 24-28, 31, 34-36, 38 and 39 remain in this application. Claims 16 and 38 have been canceled. Claims 1, 12 and 24 have been amended to replace the phrase "data collection means" with patient data comprising at least one type of data selected from the group consisting of physical examination data, laboratory data, and patient history data. Support for this amendment can be found throughout the specification, at least in paragraph [0081]. Claims 2 and 13 have been amended to comport with the amendments to claims 1 and 12.

Claims 1, 10, 12, 22, 27, 36 and 39 have been amended to recite that the disease is HIV-related disease.

Claims 5 and 31 have been amended to remove the data interpretation means "physician specialist."

No new matter has been introduced as a result of the claim amendments

35 U.S.C. §112 Rejections

Claims 12, 38 and 39 are rejected under 35 U.S.C §112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. The Office asserts that "[a] claim cannot refer to a figure within the body of a claim." Office Action dated May 13, 2010 (hereinafter "OA"), page 2, paragraph 7. Applicants respectfully disagree.

Claim 38 has been canceled. Claims 12 and 39 recite the use of the algorithm of Figure 4 as the data interpretation means. Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). MPEP §2173.05(s)

Applicants respectfully assert that there is no practical way to incorporate the algorithm of Figure 4 into the claims other than incorporation by reference. Therefore, Applicants respectfully request that the Office allow the recitation of Figure 4 in claims 12 and 39 and withdraw the rejection on this basis.

35 U.S.C. §101 Rejections

I. Claim 39 has been rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter.

Claim 39 has been amended to recite that the data is interpreted according to the algorithm of Figure 4 such that a diagnosis is established and/or at treatment regimen is proposed and the therapeutic agent is dispensed based upon the diagnosis and/or treatment regimen. Claim 39, as now written, recites the interpretation of patient data with the algorithm of Figure 4 to arrive at a diagnosis and/or a treatment regimen and the dispensing of a therapeutic agent based on the diagnosis and/or treatment regimen. Applicants respectfully assert that in its amended form, claim 39 transforms the patient

data into a treatment plan leading to the dispensing of a therapeutic agent. Thus, Applicants respectfully request that the rejection on this basis be withdrawn.

II. Claims 1, 2, 5, 8-10, 12-13, 16, 18, 20-22, 24-26 and 31 has been rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter.

Claims 1, 12, and 24 have been amended to replace the phrase "data collection means" with "patient data selected from the group consisting of physical examination data, laboratory data and patient history data." Claims 2, 5, 13 and 31 have been amended to comport with the amendments to claims 1, 12, and 24.

Based on the amendments to claims 1, 2, 5, 12, 13, 24 and 31, Applicants respectfully request that the rejection on this basis be withdrawn.

35 U.S.C. §103 Rejections

I. Claims 1, 2, 5, 8, 12, 13, 16, 18, 20, 24, 27, 28, 31, 34, 38 and 39 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Linberg et al. (US 2001/10039504 A1). Applicants respectfully disagree.

To maintain a proper rejection under 35 U.S.C. § 103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a teaching, suggestion, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be

applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

The instant claims are directed to disease management systems and methods of managing disease comprising remote data collection from a non-physician healthcare worker or laboratory comprising physical examination data, laboratory data and patient history data; data interpretation means comprising the algorithm of Figure 4; and dispensing of therapeutic agents or treatments based on the results of the data interpretation.

Linberg teaches methods of remotely managing implantable medical devices using the Internet and World Wide Web technologies.

Applicants respectfully assert that Linberg does not teach or suggest all the limitations of the pending claims, is non-analogous art and teaches away from the instantly claimed invention.

A. Linberg does not teach or suggest all the claim limitations.

Linberg does not teach or suggest all the limitations of the claimed invention. Linberg's data collection means is an implantable medical device (see paragraph [0010] of Linberg). The instant claims have been amended to clarify that the data collection is patient data comprising at least one of physical examination data, laboratory data and patient history data.

Linberg does not teach or suggest the algorithm of Figure 4, which is the data interpretation means. Furthermore, Linberg does disclose an algorithm for determining a treatment regimen for disease management of HIV-related disease.

Therefore, Linberg does not teach or suggest all the claim limitations of the pending claims.

B. Linberg is non-analogous art to the claimed invention.

Determining whether art is analogous and appropriate to combine under 35 U.S.C. §103 involves a two-part inquiry. First, to be analogous, the art must be "within the field of the inventor's endeavor." *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986). If the art is outside the inventor's field of endeavor, art is only analogous if it is "reasonably pertinent to the particular problem with which the inventor was involved." *Id.* References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). ("[I]t is necessary to consider 'the reality of the circumstances,' – in other words, common sense – in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." (*In re Wood*, 599 F.2d 1032, 1036 (C.C.P.A. 1979)). This test begins the inquiry into whether a skilled artisan would have been motivated to combine references by defining the prior art relevant for the obviousness determination, and that it is meant to defend against hindsight. *See id.*; *In re Clay*, 966 F.2d 656, 659-60 (Fed. Cir. 1992).

The inventor's field of endeavor is determined from "the scope explicitly specified in the background of the invention." *In re Wood*, 599 F.2d 1032, 1036 (C.C.P.A. 1979). Here, the specification states that "the present invention provides advanced diagnostic, prognostic and therapeutic capabilities to healthcare workers located in remote, rural and resource-poor urban centers." (paragraph [0003]) The Background of the Invention also states "[e]ven as the political will has evolved toward an aggressive management plan, there is limited infrastructure to administer HAART to the urban population, even less so to those dispersed in remote rural areas." Paragraph [0010]. Thus, the present field of endeavor is to manage disease in resource-poor, remote and rural areas.

In contrast, Linberg proposes a technology-focused approach to managing advanced medical care, that is, use of sophisticated technology-driven implantable medical devices. Furthermore, the method of Linberg requires the use of a computer at the data collection location to collect the data. Applicants respectfully assert that the

field of endeavor of Linberg is the management of a highly sophisticated technology, medical devices, in a resource-rich environment.

In *Monarch Knitting*, the Federal Circuit held that in applying the two-step test to determine whether art is analogous, it is error to define “the problem in terms of its solution” because this involves “improper hindsight in the selection of the prior art relevant to obviousness.” *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139, F.3d 877 (Fed. Cir. 1998). Stated another way, just because both the instant claims and Linberg both disclose management of patient data where the patient and data collection are remote to the data analysis, this common feature does not serve to bring them into a common field of endeavor. See, for example, *In re Clay*, 966 F.2d at 659 (“[The reference] cannot be considered to be within [the inventor’s] field of endeavor merely because both relate to the petroleum industry.”).

The problem addressed by the present inventors was the need for management of patients infected with HIV in areas lacking sophisticated medical resources. Linberg is not reasonably pertinent to this goal because it relates to the use of sophisticated technology to manage sophisticated medical devices. Therefore, a person of ordinary skill in the art would not reasonably seek to apply a reference from this non-analogous field. Considering the ‘reality of the circumstances’ as required under *In re Wood*, there is no motivation to look to the medical device monitoring arts to solve the problem of management of disease in resource-poor, rural and remote areas. See, for example, *United States Surgical Corp. v. Hospital Products International PTY Ltd.*, 701 F. Supp. 314 334 (D. Conn. 1988) (“The evidence indicates that the paper stapling art is not one that would lend itself to the resolution of the problems encountered in surgical stapling...”); *Schneider (Europe) AG v. SciMed Life Systems, Inc.*, 852 F. Supp. 813, 853 (D. Minn. 1994) *aff’d*, 60 F.3d 839 (Fed. Cir. 1995) (unpublished), *cert. denied*, 516 U.S. 990 (1995) (“Combining devices that have a short guide wire lumen, but are not used in dilation or coronary dilation, with ... Percutaneous Transluminal Coronary Angioplasty devices that have a long guide wire lumen, would not have been obvious to one of ordinary skill because they would not have been reasonably pertinent to the particular problem with which [the inventor] was concerned.”).

Therefore, Applicants respectfully assert that the subject matter of the instant claims and Linberg are non-analogous arts and Linberg is not pertinent to the problem sought to be solved by the present invention.

C. Linberg teaches away from the claimed invention.

"A prior art reference must be considered in its entirety, i.e., as a whole, including portions which would lead away from the claimed invention." *W.L. Gore & Associates, Inc. V. Garlock, Inc.* 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Thus, Applicants assert, when considering the reference as a whole, the Linberg reference actually leads away from the claimed invention and does not render it obvious because the teachings of Linberg require expensive, sophisticated technologies (computers and medical devices) not available in resource-poor, remote and rural areas. The instant invention overcomes this barrier to disease management by requiring patient data only comprising physical exam data, laboratory data and patient history data to be collected at the location remote to the data interpretation means. Moreover, Linberg does not discuss whatsoever the problems solved by the present invention, namely, a method of managing disease in resource poor, remote or rural setting where there is a lack of trained physicians and modern, technology-rich medical facilities.

Therefore, Applicants respectfully assert that the Office has not established *prima facie* obviousness of the pending claims because Linberg does not teach or suggest all the limitations of the pending claims, is non-analogous art and teaches away from the instantly claimed invention. Applicants respectfully request withdrawal of the rejection on this basis.

II. Claims 9, 21, 25 and 35 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Linberg in view of Barry (US 6,188,988 B1). Applicants respectfully disagree.

As discussed *supra*, the pending claims are not obvious over Linberg. Barry was included for its disclosure of computer-readable medium, patient histories and CD4 levels. However, the combination of Linberg and Barry does not disclose all the limitations of the pending claims, including but not limited to the algorithm of Figure 4.

Therefore, Applicants respectfully assert that the Office has not established *prima facie* obviousness of the pending claims because the combination of Linberg and Barry does not teach or suggest all the limitations of the pending claims and Linberg is non-analogous art and teaches away from the instantly claimed invention. Applicants respectfully request withdrawal of the rejection on this basis.

III. Claims 10, 22, 26 and 36 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Linberg et al. in view of Sperber (US 2004/0197770 A1).

As discussed *supra*, the pending claims are not obvious over Linberg. Sperber was included for its disclosure of treatments for HIV-related diseases. However, the combination of Linberg and Sperber does not disclose all the limitations of the pending claims, including but not limited to the algorithm of Figure 4.

Further, Linberg and Sperber are non-analogous art. The field of endeavor for the instant claims and for Linberg has been discussed *supra* and are the management of disease in resource-poor, remote and rural areas, and the management of highly sophisticated medical devices in a resource-rich environment, respectively. Sperber's field of endeavor is the treatment of disease associated with HIV-1 infections by decreasing, inhibiting or otherwise abrogating cell apoptosis. Therefore, Linberg and Sperber are neither analogous art to each other nor analogous art to the presently claimed invention.

Therefore, Applicants respectfully assert that the Office has not established *prima facie* obviousness of the pending claims because the combination of Linberg and Sperber does not teach or suggest all the limitations of the pending claims, are non-analogous art to each other and to the instant claims, and Linberg teaches away from

the instantly claimed invention. Applicants respectfully request withdrawal of the rejection on this basis.

CONCLUSION

In light of the claim amendments and argument presented *supra*, Applicants respectfully assert that the pending claims are in condition for allowance and request that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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